



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/803,458	02/20/97	MATSUMOTO	1 6208.570

MYERS LINIAK AND BERENATO  
SUITE 240  
6550 ROCK SPRING DRIVE  
BETHESDA MD 20817

18M2/0825

EXAMINER

SAULTIER, S

ART UNIT	PAPER NUMBER
1808	

DATE MAILED: 08/25/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/803,458</b>	Applicant(s) <b>Matsumoto</b>
	Examiner <b>Sandra Saucier</b>	Group Art Unit <b>1808</b>

Responsive to communication(s) filed on Jul 14, 1997.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) 3-5 and 7-9 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, and 6 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

Claims 1-9 are pending. Claims 1, 2 and 6 are considered on the merits. Claims 3-5, 7-9 are withdrawn from consideration as being drawn to a non-elected invention.

***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 3 is acknowledged. The traversal is on the grounds that the inventions are not independent and that it would not be a burden to search them together. This is not found persuasive because burden is found not only in the search, but in the prosecution of independent inventions. Further, if the processes are not believed to be distinct by applicants, applicants may admit on the record that a reference which anticipates or makes obvious one group, will be accepted as anticipatory or making obvious all groups. Distinct means patentably distinct. The claimed methods have distinct steps and yield distinct products. Therefore, they patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

**INDEFINITE**

Claims 1, 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,2 and 6 recite "short period" in step (c). This term has no reference point and therefore makes the claims indefinite.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The examples use the two solutions, RLB and BELMAR produced by the Harajuku Clinic. It is not clear whether or not these solutions are commercially available. Nor is there any description given of the components of these solutions. If the solutions are commercially available, catalog pages describing the solutions would provide evidence of enablement. The specification only recites the use of hypotonic or hypertonic solutions and does not give any values of osmolality, or the components of these solutions. The method is an empirical one and involves the production of uncharacterized cell fractions,

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which are produced only with RLB and BELMAR solutions. Thus, one of skill in the art would not have sufficient guidance to practice the invention as claimed.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in *In re Fisher*, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.]]

#### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

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in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 102 (b) or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Miyaki et al. [U] or Gabay et al. [V] or Pereira et al. [X] or US 5459235 [A].

Miyaki et al. is a review which discloses blood cell carried proteins which have antimicrobial activity. For example, defensins, cathepsin G, calprotectin are all synthesized by neutrophils.

Gabay et al. is a review which discloses blood cell carried proteins which have antimicrobial activity. For example, defensins, serprocidins and others.

Pereira et al. disclose CAP57 and CAP37, synthesized by leukocytes, which has antibiotic activity.

US 5459235 discloses that blood cells contain antimicrobial proteins, such as defensins.

It is reasonable to assume that the treatment of the blood cells in the claimed method would rupture them or cause leakage of the various intracellular proteins known to have antibiotic activity. Thus, the composition as claimed in a product by process claim, is either the same or so close as to be patentably indistinct from or obvious over the disclosed compositions.

Mere discovery of a new process to make an old material does not confer patentability on the old material.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs and, if so, to what extent from the composition discussed in the references. Accordingly, it has been established that the prior art composition, which has the same origin and shares the antibiotic property of the claimed composition demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

#### ***Claim Rejections - 35 USC § 103***

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5459235 [A] in view of Valeri [Y].

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The claims are directed to a process of fractionating blood, taking a upper layer after dextran fractionation, subjecting the upper layer to a hypotonic then a hypertonic solution.

US 5459235 discloses a method of fractionating blood comprising sedimenting in a centrifuge, taking the erythrocyte column, subjecting it to hypotonic conditions for 7 secs. and then adding a hypertonic solution (example 1, col. 11, l. 30-35). The fraction so obtained contains antimicrobial proteins, beta defensins. Missing from this reference is fractionation of the cells with dextran.

Valeri discloses that blood may be fractionated by centrifugation or sedimentation with dextran, page 1, col. 2.

It would have been obvious to fractionate blood cells with dextran in place of the centrifugal method of US 5459235 when the primary reference was taken with Valeri who discloses that cells may be separated with dextran or with centrifugation. The choice of separation techniques is an element of experimental design and is within the purview of one of skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries may be directed to the Service Desk at (703) 308-0196. The numbers of the Fax Center for the faxing of papers are (703) 305-4242 and (703) 305-3014.



Sandra Saucier  
Primary Examiner  
Art Unit 1808  
August 13, 1997